The Monsanto Papers: Poisoning the scientific well

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Abstract.

OBJECTIVE: Examination of de-classified Monsanto documents from litigation in order to expose the impact of the company's efforts to influence the reporting of scientific studies related to the safety of the herbicide, glyphosate.

METHODS: A set of 141 recently de-classified documents, made public during the course of pending toxic tort litigation, *In Re Roundup Products Liability Litigation* were examined.

RESULTS: The documents reveal Monsanto-sponsored ghostwriting of articles published in toxicology journals and the lay media, interference in the peer review process, behind-the-scenes influence on retraction and the creation of a so-called academic website as a front for the defense of Monsanto products.

CONCLUSION: The use of third-party academics in the corporate defense of glyhphosate reveals that this practice extends beyond the corruption of medicine and persists in spite of efforts to enforce transparency in industry manipulation.

Keywords: Carcinogenicity, conflicts of interest, ghostwriting, genotoxicity, glyphosate, herbicides, Intertek, key opinion leaders, Monsanto, non-Hodgkins lymphoma, third parties, Roundup

The best-laid schemes o' mice an' men

Gang aft agley.

—Robert Burns

1. Introduction

Corporate misrepresentation of scientific testing facilitated by third-party academic consultants is now well documented in medicine [1–3]. The crucial components of the third-party strategy include ghostwriting, the creation of decoy research, marketing spin and public relations campaigns designed to discredit and intimidate critics. As McGarity and Wagner made the point in *Bending Science*:

...advocates infiltrate the pipeline and secretly situate themselves at various key points to ensure that research, the critiques, the panel reports, and the overall messages match their ends. In other cases, they undermine the work of scientists who persist in conducting research that runs contrary to their goals [4, p. 5].

Industry-contaminated science has alarming consequences for public health as misrepresentations pass through the system undetected by regulatory agencies and the courts that rely on evidence-based results.

In the case of the pharmaceutical and medical device firms, academic consultants or "key opinion leaders" are identified for their influence on medical practice and prescribing behavior. They are carefully vetted for their willingness to be "product champions" and thereby become members of advisory

boards, speaker's bureaus, "authors" on ghostwritten journal articles and agents of off-label promotion [5, p. 996]. Branding industry's products with the academic reputation and institutional affiliation of key opinion leaders is an important feature of the consulting arrangement between companies and third-party experts. The more prestigious the academics' university affiliation, the more highly sought after they are in the process of gaining credibility for industry's claims of safety and efficacy of their products. When, however, problems emerge from the misrepresented science, the harms to patients' health can be severe. Examples from recent cases include: addiction, iatrogenic illness, birth defects, drug-induced suicide, congestive heart failure, stroke, heart attack and botched surgeries involving faulty medical devices [2, 6, 7].

The purpose of this article is to evaluate the impact of the third-party strategy beyond the pharmaceutical and medical device industries. In this case study from on-going litigation I examine the efforts of agrochemical giant Monsanto to influence the reporting of scientific results related to the safety of the herbicide Roundup, and its active chemical, glyphosate. This article will not offer an opinion about any particular study concerning the safety of Roundup or glyphosate as that project is beyond the scope of this paper and requires expertise in each of the various areas of scientific investigation.

2. The Monsanto Papers

"The Monsanto Papers" is a set of 141 recently de-classified documents, made public during the course of pending toxic tort litigation, *In Re Roundup Products Liability Litigation*, 3:16-md-2741, Northern District of California. The documents include: internal Monsanto emails, manuscript drafts, peer review reports, deposition testimony, powerpoint presentations and text messages. Plaintiffs' attorneys sought the release of these documents on the grounds that none contain trade secrets that are the basis for maintaining confidentiality. These documents and others obtained from Freedom of Information Act (FOIA) requests are posted on the websites of U.S. Right to Know (https://usrtk.org/pesticides/mdl-monsanto-glyphosate-cancer-case-key-documents-analysis/) and the law firm of Baum, Hedlund, Aristei & Goldman (https://www.baumhedlundlaw.com/toxic-tort-law/monsanto-roundup-lawsuit/monsanto-secret-documents/). The public release of the Monsanto Papers was controversial since there was a legal dispute over whether the case's protective order had been violated. Monsanto's attorneys sought sanctions from the court against the plaintiffs for the release of some of the documents. This request was denied.

3. IARC controversy over glyphosate

Glyphosate (N-(phosphonomethyl)glycine) was first used as a descaling agent for cleaning mineral deposits in industrial boilers and pipes. When glyphosate's waste by-product was deposited in nature, it was discovered that it killed plants. Monsanto then developed the molecule in the early 1970s as an herbicide. It is the active ingredient in the herbicide that was subsequently marketed by Monsanto as Roundup[®] and registered in the United States in 1974 [8]. Until recently, it has been considered safe for use on crops, lawns and gardens.

As Blair et al. state:

Pesticides, including herbicides, insecticides, fungicides, fumigants and rodenticides, provide important benefits in public health, food production and aesthetics... Unlike most other important chemicals, pesticides are designed to impact living systems ... Consequently there has long been a concern about environmental and human consequences of widespread pesticide use [9, p. 81].

The International Agency for Research on Cancer (IARC), a World Health Organization agency, was created to investigate epidemiological and laboratory research into the causes of human cancer. In 2014, an international advisory group of senior scientists and government officials recommended dozens of pesticides for evaluation, which included glyphosate. In March, 2015, the IARC Working Group published its findings that glyphosate is a Group 2A agent—probably carcinogenic in humans [10, p. 78]. The IARC Working Group concluded epidemiology supported glyphosate's carcinogenicity in humans, and a positive association had been observed for non-Hodgkins lymphoma, although confounding factors could not be ruled out. This conclusion was also based on strong evidence from mechanistic data that glyphosate causes genotoxicity and oxidative stress [10, pp. 77, 78].

The Monsanto Company vigorously disputes the IARC conclusion. A posted response to the IARC Report on Glyphosate on the company's website states: "In evaluations spanning four decades, the overwhelming conclusion of experts worldwide has been that glyphosate, when used according to label directions, does not present an unreasonable risk of adverse effects to humans, wildlife or the environment" [11]. The reference to "the overwhelming conclusion of experts worldwide" is of particular interest given what the Monsanto Papers reveal. It appears that Monsanto not only anticipated the carcinogenic classification for glyphosate and glyphosate-based formulations, but pro-actively engaged third-party academics who acted on Monsanto's behalf as "independent" experts in signing onto Monsanto ghostwritten reports which were then published in leading toxicology journals and in the lay media. Toxicology Manager at Monsanto, David Saltmiras, described this goal as part of what he called "Glyphosate Freedom to Operate" when he listed in his accomplishments the publication of a review manuscript of rodent chronic/carcinogenicity studies in preparation for a possible IARC review of glyphosate [12]. Internal communications regarding the IARC Evaluation of Glyphosate show that Monsanto's scientists believed that Saltmiras had "the animal onco[logy] studies under control" but identified vulnerabilities in the areas of epidemiology, exposure, genetoxicity and mode of action [13].

When the planned IARC meeting was announced late in 2014, Monsanto's Donna Farmer wrote to former employee, John Acquavella, in an email of 9/18/2014: "Just wanted to let you that what we have long been concerned about has happened. (sic) Glyphosate is on for an IARC review in March of 2015." Farmer then wrote: "Glyphosate had been listed as a medium priority for 2015-2016 but clearly something happened and it got *moved* up to an ultra priority" and identified consultants Tom Sorahan and Sir Colin Berry for moving forward [14].

4. Manufacturing doubt: Ghostwriting the reports

Since articles written by industry employees may be considered to have little credibility, for-profit industries rely on third parties to give their publications the appearance of an independent, objective, scientific assessment and thereby increase the likelihood of acceptance by the relevant journals. Ghost-writing is the practice in which the companies secretly author journal articles in the names of prominent academic researchers in order to build a literature base to support products and neutralize criticism [6, 15, 16]. Ghost authorship is the failure to name, as an author, an individual, typically an employee of a pharmaceutical company or medical communication firm, who has made substantial contributions to the research or writing of the article [17, p. 222]. Ghostwriting toxicology publications for glyphosate sponsored by Monsanto indicates the practice might be more widespread than previously suspected.

In a rare statement of intention in which Monsanto executives actually described their activities as ghostwriting, an email dated 2/19/2015, one month prior to the release of the IARC report on glyphosate, titled: RE: IARC Planning, William Heydens, Regulatory Product Safety Assessment Lead at Monsanto, wrote:

If we went full-bore, involving experts from all major areas (Epi, Tox, Genetox, MOA, Exposure – not sure who we'd get), we could be pushing \$250K or maybe even more. A less expensive/more palatable approach might be to involve experts only for the areas of contention, epidemiology and possibly MOA (depending on what comes out of the IARC meeting), and we ghost-write the Exposure and Tox & Genetox sections. An option would be to add Greim and Kier or Kirkland to have their names on the publication, but we would be keeping the cost down by us doing the writing and they would just edit & sign their names so to speak. Recall this is how we handled Williams Kroes & Munro, 2000 [18].

In another email dated 5/11/2015, RE: Post-IARC Activities to Support Glyphosate, Heydens wrote: "Manuscript to be initiated by MON as ghost writers. It was noted that this would be more powerful if authored by non-Monsanto scientists (e.g., Kirkland, Kier, Williams, Greim, and maybe Keith Solomon). Decide within 1-2 weeks if we recommend going forward with this" [19].

Monsanto hired Intertek Scientific & Regulatory Consultancy to organize an ostensibly independent Expert Panel for the purpose of conducting an evaluation of the IARC data. What the released documents demonstrate is that the Expert Panel was anything but an independent collection of neutral scientists rendering an opinion on the carcinogenicity of glyphosate. Moreover, Intertek employees assisted in the ghostwriting of the report that was published under the title, "A Review of the Carcinogenic Potential of Glyphosate by Four Independent Expert Panels and Comparison to the IARC Assessment" in Critical Reviews in Toxicology [20]. In an email dated 2/9/2016 to Intertek's Ashley Roberts, re: Summary Article, William Heydens wrote: "OK, I have gone through the entire document and indicated what I think should stay, what can go, and in a couple of spots I did a little editing..." [21]. The attached draft manuscript shows that Heydens made substantial edits, some of which overruled what named authors had deleted as inflammatory of IARC, and marginalia comments that demonstrated that he controlled the manuscript. Many of his comments, for example, state that he "can live with" certain edits that others had made to the manuscript. Heydens also noted that the named authors had "over-stepped the bounds" in deleting certain statements that he wished to retain. A comparison of the working draft attached to the 2/9/2016 email with the published Williams et al. article confirms that Heydens's edits were final. In another email dated 1/6/2016 to Intertek's Ashley Roberts, re: Glyphosate Expert Panel Manuscripts, Heydens wrote: "I had already written a draft Introduction chapter back in October/November, but I want to go back and re-read it to see if it could benefit from any 're-freshing' based on things that have transpired over the last 10-12 weeks" [22]. In neither the Acknowledgements nor the Declaration of Interest in the Williams et al. article is there any mention of Heydens' contribution to the article. Since Heydens is not included as an author in the by-line of the published article, he qualifies as a corporate ghost author. What the documents do not reveal, however, is to what degree the sixteen named authors on the article qualify for genuine authorship.

The question of the ethical permissibility of ghostwriting arose when, in the course of assigning authorship, a member of the Expert Panel and former Monsanto employee, John Acquavella, was excluded from a poster planned for a 2015 SRA [Society for Risk Analysis] meeting. In response Heydens wrote in an email to Acquavella dated 11/3/2015: "I thought we discussed previously that it was decided by our management that we would not be able to use you or Larry [Kier] as Panelists/authors because of your prior employment at Monsanto...." Acquavella responded: "I didn't realize that Bill. Also, I don't think that will be okay with my panelists. We call that ghost writing and it is unethical." In another email to Heydens in the same email chain, Acquavella wrote: "I can't be part of deceptive authorship on a presentation or publication. Please note the ICJME guidelines that everybody goes by to determine what is honest/ethical authorship" [23]. In this email, Acquavella inserted the International Committee of Medical Journal Editors (ICJME) Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals, which states:

Authorship credit should be based on (1) substantial contributions and design, acquisition of data, or analysis and interpretation of data; (2) drafting the article or revising it critically for important intellectual content; (3) final approval of the version to be published and (4) agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. Authors should meet conditions 1, 2 and 3 and 4 ... All persons designated as authors should qualify for authorship and all those who qualify should be listed ... [24].

Acquavella's objection was that he satisfied authorship criteria and therefore should be listed as an author. Having brought the ICJME criteria to Heydens' attention, Acquavella and consultant Larry Kier were subsequently included on the poster and named as authors in the publication, but Heydens, as noted above, was not.

Monsanto's IARC response-blitz also included ghostwriting for the on-line version of *Forbes* magazine. Monsanto's Eric S. Sachs wrote to Henry I. Miller at Stanford University's Hoover Institution on 3/12/2015, re: IARC Outcomes, Process and Response asking: "Are you interested in writing more on the topic of the IARC panel, its process and controversial decision? I have background and can provide information if needed. The outcome is embargoed but will be communicated as early as next week." Miller responded: "I would be if I could start from a high-quality draft. I'm absolutely inundated with projects right now." And Sachs replied: "We have a draft nearly done and will send to you by tomorrow" [25]. In the piece that appeared on Forbes.com on 3/20/2015, "March Madness from the United Nations," the following statements are made:

The data (and a selected set of data, at that) were reviewed to determine whether glyphosate is capable of causing cancer. As with common chemicals like sugar, salt and water, and foods like nutmeg and licorice, glyphosate at very high doses is capable of causing harm to humans. That's what the IARC '2A' designation—'probably carcinogenic to humans'—essentially means. But one of the seminal tenets of toxicology is that 'the dose makes the poison,' and the reality is that glyphosate is not a human health risk even at levels of exposure that are more than 100 times higher than the human exposures that occur under conditions consistent with the product's labeling [26].

Monsanto subsequently posted this part of the article on their website under the title: "What Others are Saying: Third Party Responses to IARC Glyphosate Classification 03.30.15 to 04.08.15 Independent Expert Opinions" [27]. After seeing these documents posted among the Monsanto Papers, *Forbes* removed the article from its website and terminated its relationship with Miller for failing to disclose conflicts of interest and for publishing content that was not his own original writing.

The references to Greim, Kier and Kirkland in the emails above reveal the influential third-party voices giving credibility to the Monsanto-sponsored manuscripts. According to the released documents, Monsanto ghostwrote Kier and Kirkland, "Review of Genotoxicity Studies of Glyphosate and Glyphosate-Based Formulations" [28] and Griem et al., "Evaluation of Carcinogenic Potential of the Herbicide Glyphosate, Drawing on Tumor Incidence Data from Fourteen Chronic/Carcinogenicity Rodent Studies" [29], both of which appeared in *Critical Reviews in Toxicology*.

Monsanto had devised a manuscript clearance procedure that shows the manuscript is their intellectual property cleared by legal review for submission to a journal. In the case of the Kier and Kirkland article, the manuscript clearance form identifies Monsanto's David Saltmiras and consultant Larry Kier as the named authors on the paper. The stated purpose of the publication is specified as "a valuable resource in future product defense against claims that glyphosate is mutagenic or genotoxic" [30]. The Reviewer Guidelines on the clearance form make it clear that the Regulatory Team's responsibility is to "[e]nsure that the manuscript is consistent with the Regulatory and Biotechnology publication

strategy." Moreover, the guidelines appear to prohibit any ghost authorship. One states the policy as follows: "Ensure that individuals that have contributed substantial, direct, intellectual work to this manuscript are included as authors and other significant contributors are appropriately acknowledged" [30]. When the article was published, however, Saltmiras disappeared as first author and David Kirkland's name was added in what appears to be an explicit violation of Monsanto's own policy. Saltmiras, now a ghost author, is mentioned in the Acknowledgement section of the article for his "thoughtful review of the manuscript" [28, p. 311]. In an email dated 7/18/2012, nearly five months after the manuscript had been submitted for internal clearance, Monsanto's Christophe Gustin explained that Saltmiras stepped down as co-author since the paper would pool data from confidential Taskforce Member studies and when combining reviews of a large number of studies reporting on genotoxic effects, the story stretched the limits of credibility. Kirkland was added to the project to help enhance credibility by having a renowned specialist in the area of genotoxicity. He came at the high price of £14,000 for an estimated 10 days of work, but as Saltmiras explained in an email in the same chain, "we are effectively doubling the cost of the combined projects, but reaping significant value/credibility from David Kirkland's involvement. Given the growing number of questionable genotoxicity publications, in my mind this is worth the additional cost" [31].

Similarly, Helmut Greim, a member of Monsanto's IARC Response Expert Panel, appears as the first author on "Evaluation of Carcinogenic Potential of the Herbicide Glyphosate, Drawing on Tumor Incidence Data from Fourteen Chronic/Carcinogenicity Rodent Studies" [29] but according to another of Saltmiras' performance reports on Glyphosate Activities, he "ghost wrote [the] cancer review paper Greim et al. ..." [32]. Since, however, Saltmiras is the second author on this published article, it is unclear how he is using the term "ghost wrote." If the plan as explained in Heydens' email was implemented in this paper as well, i.e., that Greim and others named as 'authors' "would just edit & sign their names" [18], then the more accurate term to describe their role would be "honorary authors" and Saltmiras' role, in organizing their participation, as the "ghostmanager" of the project.

Williams et al. "Safety evaluation and risk assessment of the herbicide Roundup and its active ingredient, glyphosate, for humans," [33] is cited in both Greim et al. and Kier and Kirkland [28, 29]. Since Heydens' email dated 2/19/2015 informs his Monsanto colleagues that this paper was handled in the same manner as he proposed for Greim, Kier and Kirkland [18], this raises the question of how many of the other articles cited as support for the safety of Roundup and glyphosate are also Monsanto-ghostwritten articles. Aside from the deception involved in any one ghostwritten article, once published, these articles perpetuate misrepresentations well into the future by citing other ghostwritten articles.

5. Monsanto's interference in peer review and the retraction of Séralini et al.

A Monsanto toxicologist, Charles Healy, when asked by the editor of *Cell Biology and Toxicology* to peer review a manuscript that raised problems with glyphosate, inappropriately sent the manuscript to Monsanto employees and asked for their input. The manuscript (CBTO548) titled, "Cytotoxicity of Herbicide Roundup and its Active Ingredient, Glyphosate in Rats," submitted in 2008 reported the results of a study that sought to analyze potential cytotoxicity of Roundup and its fundamental substance (glyphosate) and to investigate whether glyphosate alone or glyphosate included in Roundup affected hepatic glutathione (GSH) and lipid peroxidation (LPO) levels of animals as an index of antioxidant status and oxidative stress. The authors found that:

Roundup induced significant changes in cellular antioxidant status as GSH depletion and increased LPO more than Glyphosate. Significant time-dependent depletion of GSH levels and induction of oxidative stress in liver by the elevated levels of LPO, further confirmed the potential of Roundup to induce oxidative stress in hepatic tissue. However, glyphosate caused

significant increases in NO [nitric oxide] levels more than Roundup after two weeks of treatment. Both treatments increased the level of TNF-<alpha>[alpha tumor necrosis factor] by the same manner [34].

In an email of "High Importance" dated 8/19/2008, Healy forwarded the invitation that had been offered to him by the journal's editor, John Masters, to review the manuscript to fellow Monsanto colleagues, David Saltmiras and Donna Farmer, asking them whether they would be the reviewers and he would then collate their comments and be the reviewer of record [34]. After Healy submitted a five-page recommendation to John Masters urging him to reject the manuscript [35], Healy received an email dated 9/9/2008 in which Masters reported that he had completely opposite reviews on the paper and asked once again for comments before giving the manuscript's authors a final decision. Healy once again forwarded the editor's email to Saltmiras and Farmer, with the remark: "Looks like ours will be the deciding vote as to whether the glyphosate paper is published," and requested that Saltmiras and Farmer provide him with their input [36]. In spite of what appears to be Monsanto's efforts to block publication, the paper appeared one year later as "Oxidative stress responses of rats exposed to Roundup and its active ingredient glyphosate" in *Environmental Toxicology and Pharmacology* [37].

What is missing from the documentary evidence is exactly what input Saltmiras and Farmer contributed to Healy's peer review report even though the email of 9/9/2008 does permit the inference that the recommendation was the work of Monsanto employees Saltmiras and Farmer, not Healy. In any case it was certainly a violation of the standards of peer review that Healy was credited with being the reviewer of record on a peer review report that was apparently ghostwritten by two others. It is questionable as to why a manuscript for review on the safety of Roundup and glyphosate was sent by the journal editor of *Cell Biology and Toxicology* to an employee of the manufacturer in the first place.

In an article by Séralini et al., "Long Term Toxicity of a Roundup Herbicide and a Roundup-Tolerant Genetically Modified Maize," published in *Food and Chemical Toxicology* in 2012, a two-year feeding-study of rats reported an increase in tumors among rats fed genetically modified corn and the herbicide Roundup [38]. The study was controversial due to suspicions that genetically modified (GM) foods pose a human health risk and because the lead author, Gilles-Eric Séralini, is co-founder and member of the Scientific Council of an anti-GM organization, Committee of Research and Independent Information on Genetic Engineering, (CRIIGEN), that sponsored his research. After the publication of critical responses to the Séralini et al. article in 2013, the editors determined that the study was inconclusive and retracted the article in an official notice that stated in part: "Very shortly after the publication of this article, the journal received Letters to the Editor expressing concerns about the validity of the findings it described, the proper use of animals, and even allegations of fraud. Many of these letters called upon the editors of the journal to retract the paper" [39]. This, however, only fueled further debate in letters to the editor and the authors of Séralini et al. republished the study in *Environmental Sciences Europe* [40].

What has been omitted from various reports thus far about what has been dubbed "The Séralini Affair" is the role that Monsanto played in the behind-the-scenes retraction and in the apparent pressure that Monsanto's employees exerted on the journal's editor, A. Wallace Hayes, who had the final authority to retract. As a member of the Issues Management Team, Saltmiras reported in his Business Performance for 2013 that he had leveraged his relationship with the Editor-in-Chief of *Food and Chemical Toxicology* throughout the 2012 Séralini rat cancer publication and media campaign and boasted that he had "successfully facilitated numerous third party expert letters to the editor which were subsequently published, reflecting the numerous significant deficiencies, poor study design, biased reporting and selective statistics employed by Seralini" [12].

An email chain dated 9/26/2012 between Monsanto's Heydens, Sachs, and Saltmiras shows further contact with the Editor-in Chief of *Food and Chemical Toxicology*, A. Wallace Hayes, in facilitating publication of letters to the editor that were critical of Séralini et al. Eric Sachs was tasked with contacting the third-party scientific experts to "request that they consider formal letters to the Editor," yet in the same email string, he wrote that Monsanto must not be seen as participating in a formal process to retract a publication that challenges the safety of Monsanto's products. This, he said, would "provide ammunition for Seralini, GM critics and the media to charge that Monsanto used its might to get this paper retracted" [41]. Two days later, when Monsanto's Daniel Goldstein was preparing a slide presentation on the Séralini et al. publication, Sachs suggested an edit: "Consider adding a bullet regarding – 25 scientists from 14 countries respond with letter to the editor." Goldstein responded: "Considered doing this already—but I was uncomfortable even letting shareholders know we are aware of this LTE [letter to the editor] It implies we had something to do with it—otherwise how do we have knowledge of it?... We are being asked to keep internal correspondence down on this subject" [42].

Monsanto's attack on Séralini et al. also included another *Forbes* article in the names of Henry I. Miller and Bruce Chassy, "Scientists Smell a Rat in Fraudulent Genetic Engineering Study," September 25, 2012, subsequently removed from *Forbes* website. In a 2012 lawsuit Séralini sued *Marianne* magazine and journalist Jean-Claude Jaillet for defamation after they accused him of fraud. The High Court of Paris that ruled in Séralini's favor in 2015 determined that the fraud allegation had first been made by Henry I. Miller in the *Forbes* article [43].

Whatever the demerits of Séralini et al. study, it was never found to be fraudulent nor its participants guilty of academic misconduct, in spite of the efforts of Monsanto and its third parties to establish otherwise. As David Resnik wrote in the *Journal of Agricultural and Environmental Ethics*, "inconclusiveness, by itself, is not a sufficient reason for retracting an article" [44, p. 621]. Articles should be retracted only for serious errors that undermine the reliability of the data or results or for serious ethical lapses. The retraction of Séralini et al. was a clear violation of Committee on Publication Ethics (COPE) retraction guidelines [44, pp. 627–629].

In addition to academics, Monsanto's third-party consultants also include journal editors who have enormous power to control scientific publishing. This raises even more problems for conflicts of interest with industry and the integrity of peer review. A consulting agreement between A. Wallace Hayes and Monsanto dated August 21, 2012, one month before Monsanto's campaign to retract Séralini et al., states that Hayes was to be engaged in order to establish: "an expert network of toxicologists, epidemiologists, and other scientists in South America and participate on the initial meeting held within the region." The agreement further states that Hayes would prepare and deliver a seminar addressing the relevant regional issues pertaining to glyphosate toxicology [45]. The journal Food and Chemical Toxicology also hired a former Monsanto employee, Richard Goodman, as an Associate Editor of Biotechnology just prior to the retraction of Séralini et al., fueling speculation among critics that he was hired for this purpose. Goodman received research funding from agrochemical companies, including Monsanto, while he was an editor of Food and Chemical Toxicology [46, p. 118]. Emails obtained from US Right to Know, reveal that Hayes and Goodman sought criticism from Monsanto employees in what amounted to a post-hoc second peer review of Séralini et al. Hayes and Goodman then wrote to Monsanto employee Bruce Hammond who was identified as a critic of Séralini and invited him to become a reviewer of submissions in biotechnology. Hayes wrote: "My request as the Editor-in Chief of the journal editor and on behalf of Professor Goodman is that those of you who are highly critical of the recent paper dealing with GMO by Seralini et al. (Food Chem. Toxicol. 2012) volunteer your service as potential reviewers ... " [47]. When a paper submitted to the journal in 2014 cited a report from Sri Lanka about a "possible exposure/correlation and proposed a mechanism for glyphosate toxicity related to kidney disease," Goodman wrote to Monsanto's John Vicini about reviewing an "anti-paper" and

asked him to provide some "sound scientific arguments for why this is or is not plausible" [48]. From the context, an "anti-paper" is one that is against the interests of Monsanto in defending the safety of glyphosate.

In connection with the publication of industry ghostwritten articles, there is always a question of whether journal editors are complicit in maintaining the status quo. At the time that tobacco companies were fighting against increasing negative public opinion, lawsuits and the threat of government regulation, the industry began using third-party consultants to influence the perception of science in their favor and create doubt in damaging toxicology reports about the health effects of smoking [4, pp. 81, 193]. In one of the earliest ghostwriting documents released from tobacco litigation, A. Wallace Hayes who worked for the R. J. Reynolds Tobacco Company in the 1980 s, is the author of a memorandum that details a proposal for a ghost writing program that would publish studies from toxicological investigations. The memorandum shows how ghostwritten articles would be reviewed by a panel at Reynolds prior to submission in *Cancer Research* or *The Journal of the National Cancer Institute* [49]. Tobacco companies such as R. J. Reynolds are credited with writing the playbook for spinning science subsequently adopted by pharmaceutical companies and the agrochemical industry [4, p. 27].

6. Monsanto's hidden role in Academics Review

The About page for "Academics Review: Testing Popular Claims Against Peer Reviewed Science" states that the website is an independent 501(c)3 non-profit organization founded by "two independent professors of food-related microbiology, nutritional, and safety issues," Bruce M. Chassy and David Tribe. A cursory glance at the home page reveals attacks on the 2015 IARC glyphosate cancer review, Séralini, journalists such as Carey Gillam, and tellingly the US Right to Know organization, ironically depicted as having launched a FOIA campaign against academics. What the website does not disclose is Monsanto's role in the creation of Academics Review as a third-party platform for attacking critics under the guise of "independent" professors.

According to an email chain between Monsanto's Eric Sachs and Bruce Chassy, dated 11/30/2010, re: Questions, obtained from a US Right to Know FOIA request, Chassy asked Sachs about the date by which a deposit would be completed and Sachs responded:

We sent a gift of \$10,000 to Dennis Campion's [Associate Dean, University of Illinois at Urbana-Champaign] office via Fed Ex so the funds should be there. . . . You and I need to talk more about the 'academics review' site and concept. I believe that there is a path to a process that would better respond to scientific concerns and allegations. I shared with Val [Giddings] yesterday. From my perspective the problem is one of expert engagement and that could be solved by paying experts to provide responses. You and I have discussed this in the past. Val explained that step one is establishing a 501(c)3 not-for-profit status to facilitate fund raising. That makes sense but there is more. I discussed with Jerry Steiner today (Monsanto Executive Team) and can help motivate CLI/BIO/CBI and other organizations to support. The key will be keeping Monsanto in the background so as not to harm the credibility of the information [50].

CBI, Council for Biotechnology Information, referenced in this email, turned out to be a major funding source for Academics Review. Not only is Monsanto one of the eight life-science companies in the CBI coalition, Monsanto's Vice President, Corporate Affairs, Phil Miller, is a member of the board of directors. As Cary Gilliam reports from tax filings, Academics Review received \$300,000 in 2014 and \$350,000 in 2015 from Council for Biotechnology Information [46, p. 122].

After Chassy wrote that Campion is no longer Associate Dean, Sachs responded again: "Bruce, Where should we send future gifts 'in support of biotechnology outreach' by the university? I have an additional 15,000 planned for later in the year" [50].

In another email chain between Bruce Chassy and Monsanto's former head of corporate communications, Jay Byrne, dated 3/11/2010, re: domain available, also obtained from a US Right to Know FOIA request, Chassy and Byrne discussed how Academics Review would be set up and funded. Byrne, president of v-Fluence Interactive, a market research and software development firm, wrote:

I suggest we work on the money (for all of us) first and quickly? I've proposed to Val [Giddings] that he and I meet while I'm in DC next week so we can (not via e-mail) get a clear picture of options for taking the Academic Review project and other opportunities forward. The 'Center for Consumer Freedom' (ActivitCash.com) has cashed in on this to the extreme: and I think we have a much better concept [51].

Byrne mentions topics that cross-over on all the risk areas of ag-biotech including human safety and mentions a document he says v-Fluence created for Monsanto that lists all the various areas of attack areas on ag-biotech sources and the response data available. And finally, he wrote:

All of these individuals, organizations, content items and topic areas mean money for a range of well heeled corporations. I believe Val and I can identify and serve as the appropriate (non-academic) commercial vehicles by which we can connect these entities with the project in a manner which helps to ensure the credibility and independence (and thus value) of the primary contributors/owners whil – you (sic) [51].

Both email chains stress the importance of the third-party tactic of concealing the role of the commercial sponsor and the true relationship of the third-party academics to protect the credibility of the information. But more importantly, Academics Review is a registered non-profit organization but it was apparently created to protect the profits of corporations such as Monsanto.

7. Conclusions

Whether glyphosate or glyphosate-based formulations such as Roundup are safe is a matter of objective scientific evaluation. Monsanto, however, has poisoned the well by flooding the scientific journals with ghostwritten articles and interfering in the scientific process at multiple levels. This has enormously complicated the task of discovering the truth. If the company had confidence in the safety of its products, there would be no need for such behavior, but it is obvious that there are problems that Monsanto needs to conceal.

There is a contradictory theme that appears in Monsanto's dual persona. On the one hand, the company represents itself publically as a vigorous champion of science against myths, fanaticism, emotion, politics and any failure to consider the total weight of evidence [52] and, on the other hand, it privately seeks to protect itself against possible refutation by secretly controlling the scientific process, i.e., through the purchase of prestigious academic credentials to misrepresent its own positions as those of independent scientists, manipulation of the peer review process and ghostwriting the scientific literature. The Monsanto Papers draw back the curtain and expose science on a fragile foundation, artificially propped up by corporate manipulation. For Monsanto there is no such thing as science standing as a neutral, objective test of the safety of its products; there is rather "our science" that is supportive of Monsanto's products and "their science" that does not and, as a consequence, becomes the target for a Monsanto-sponsored public relations campaign. It was in this connection that Neil Pearce warned of the alarming trend he saw in epidemiologists hired by industry to attack research not

favorable to their commercial interest and to debunk it as "junk science," including previous Monsanto misconduct. Pearce wrote: "In many instances, academics have accepted industry funding which has not been acknowledged, and only the academic affiliations of the company-funded consultants have been listed. These activities are major threats to the integrity of the field, and its survival as a scientific discipline" [53, p. 46].

Sheldon Krimsky has clearly documented the misconduct that has resulted from the academic-industry alliance that has made knowledge the property of for-profit companies. When corporations control the scientific process, the common good of humanity is replaced by the competition of special interests, all of which are engaged in marketing and promotion rather than rigorous scientific testing. As Krimsky noted: "Scientists ... whether privately or publicly funded, have a responsibility to their discipline and to the public to pursue the best science, regardless of whether or not a particular outcome adversely affects the policy or financial interests of their sponsor or themselves" [1, p. x]. Monsanto's scientists and their third-party academic experts have failed in this responsibility.

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Conflict of interest

The author has been a research consultant to the law firm Baum, Hedlund, Aristei & Goldman since 2003, during which time he has investigated nine cases of scientific misconduct involving ghostwriting.

References

- [1] Krimsky S. Science in the Private Interest: Has the Lure of Profits Corrupted Biomedical Research. Lanham: Roman & Littlefield; 2004.
- [2] Healy D. Pharmageddon. Berkeley: University of California Press; 2012.
- [3] Goldacre B. Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients. London: Fourth Estate; 2012.
- [4] McGarity TO, Wagner WE. Bending Science: How Special Interests Corrupt Public Health Research. Cambridge: Harvard University Press; 2008.
- [5] Amsterdam JD, McHenry LB, Jureidini JN. Industry- corrupted psychiatric trials. Psychiatr Pol. 2017;51(6):993-1008.
- [6] McHenry L. Of sophists and spin-doctors: Industry-sponsored ghostwriting and the crisis of academic medicine. Mens Sana Monogr. 2010;8:129-45.
- [7] Carragee EJ, Hurwitz EL, Weiner BK. A critical review of recombinant human bone morphogenetic protein-2 trials in spinal surgery: Emerging safety concerns and lessons learned. Spine J. 2011;11(6):471-91.
- [8] Franz JE. N-phosphonomethyl-glycine phytotoxicant compositions. US application 3799758 issued 1974-03-26, assigned to the Monsanto Company.
- [9] Blair A, Ritz B, Wesseling C, Freeman LB. Pesticides and human health. Occup Environ Med. 2015;72(2):81-2.
- [10] IARC. Glyphosate. In: Some Organophosate Insecticides and Herbicides: Diazinon, Glyphosate, Malathion, Parathion, Tetrachlorvinphos. IARC Working Group, March 3-10, 2015, Lyon (France). World Health Organization (WHO), International Agency for Research on Cancer (IARC) IARC Monographs on the Evaluation of Carcinogen Risks to Humans. 2015;112:1-92. Available from: http://monographs.iarc.fr/ENG/Monographs/vol112/index.php.
- [11] Monsanto. IARC's Report on Glyphosate, April 21, 2017. Available from: https://monsanto.com/company/media/statements/glyphosate-report-response/

- [12] Monsanto. MONGLY10145298. Business Performance, David Saltmiras, 20 August 2013. Available from: http://baumhedlundlaw.com/pdf/monsanto-documents/8-Monsanto-Scientist-Admits-to-Leveraging-Relationship-with-Food-and-Chemical-Toxicology-Journal.pdf
- [13] Monsanto. MONGLY00989918. Email 10/15/2014, re: IARC Evaluation of Glyphosate. Available from: http://baumhedlundlaw.com/pdf/monsanto-documents/35-Monsanto-Admits-Company-Faces-Issues-in-Epidemiology-Exposure-Genotoxicity-and-Mode-of-Action.pdf
- [14] Monsanto. MONGLY01208470. Email 9/18/2014, re: Long time. Available from: http://baumhedlundlaw.com/pdf/monsanto-documents/40-Monsanto-Executive-Expresses-Long-Held-Concerns-Over-IARC-Testing-Glyphosate.pdf
- [15] Sismondo S. Ghost Management: How much of the medical literature is shaped behind the scenes by the pharmaceutical industry? PLoS Med. 2007;4(9):e286.S.
- [16] McHenry LB, Jureidini JN. Industry-sponsored ghostwriting in clinical trial reporting: A case study. Account Res. 2008;15:152-67.
- [17] Flanagin A, Carey LA, Fontanarosa PB, Phillips SG, Pace BP, Lundbergt GD, Rennie D. Prevalence of articles with honorary authors and ghost authors in peer-reviewed medical journals. JAMA. 1998;280(3):222-24.
- [18] Monsanto. MONGLY00977264. Email 2/19/2015, re: IARC Planning. Available from: https://www.baumhedlundlaw.com/pdf/monsanto-documents/Email-Correspondence-Wherein-William-Heydens-Suggests-Experts-Could-Edit-and-Sign-Their-Names-to-Scientific-Paper.pdf
- [19] Monsanto. MONGLY01023968. Email 5/11/2015, re: Post-IARC Activities to Support Glyphosate. Available from: http://baumhedlundlaw.com/pdf/monsanto-documents/5-Monsanto-Involvement-with-Scientific-Studies-Without-Disclosing-Conflicts-of-Interest.pdf
- [20] Williams GM, Aarderna M, Acquavella J, Berry C, Brusick D, Burns MM, de Camargo JLV, Garabrant D, Greim HA, Kier LD, Kirkland DJ, Marsh G, Soloman KR, Sorahan T, Roberts A, Weed DLA. Review of the carcinogenic potential of glyphosate by four independent expert panels and comparison to the IARC assessment. Crit Rev Toxicol. 2016;46(S1):3-20.
- [21] Monsanto. MONGLY01000676. Email 2/8/2016, re: Summary Article. Available from: http://baumhedlundlaw.com/pdf/monsanto-documents/1-Monsanto-Executive-William-Heydens-Edits-and-Comments-on-Expert-Consultant-Manuscript.pdf
- [22] Monsanto. MONGLY00999487. Email 1/6/2016, re: Glyphosate Expert Panel Manuscripts. Available from: http://baumhedlundlaw.com/pdf/monsanto-documents/2-Monsanto-Executive-William-Heydens-Admits-Ghostwriting-Introductory-Chapter-in-Expert-Panel-Manuscript.pdf
- [23] Monsanto. MONGLY01030787. Emails 11/3/2015-11/4/2015, re: John, Glyphosate Expert Panel Poster at 2015 SRA Annual Meeting. Available from: http://baumhedlundlaw.com/pdf/monsanto-documents/6-Monsanto-Consultant-Protests-Ghostwriting.pdf
- [24] ICMJE. International Committee of Medical Journal Editors. Defining the Role of Authors and Contributors. Available from: http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html
- [25] Monsanto. MONGLY02063611. Emails 3/15/2015, re: IARC Outcomes, Process, and Response. Available from: http://baumhedlundlaw.com/pdf/monsanto-documents/22-Internal-Email-Demonstrating-Monsanto-Ghostwriting-Article-Criticizing-IARC-for-Press.pdf
- [26] Miller H. March Madness from the United Nations, Forbes Science and Technology, March 20, 2015. Available from: https://web.archive.org/web/20170220012554/https://www.forbes.com/sites/henrymiller/2015/03/20/march-madness-from-the-united-nations/#21e081ee2e9.
- [27] Monsanto. What others are saying: Third party responses to IARC glyphosate classification 03.30.15 to 04.08.15 Independent expert opinions. Available from: http://www.monsantoito.com/docs/What_Others_Are_Saying_Third_Party_Responses_to_IARC_Glyphosate_Classification.pdf
- [28] Kier LD, Kirkland DJ. Review of genotoxicity studies of glyphosate and glyphosate-based Formulations. Crit Rev Toxicol. 2013;43(4):283-315.
- [29] Greim H, Saltmiras D, Mostert V, Strupp C. Evaluation of carcinogenic potential of the herbicide glyphosate, drawing on tumor incidence data from fourteen chronic/carcinogenicity rodent studies. Crit Rev Toxicol. 2015;45(3):185-208.
- [30] Monsanto. MONGLY02117800. Manuscript clearance form, Review of Genotoxicity of Glyphosate and Glyphosate-Based Formulations, 2/29/2012. Available from: https://usrtk.org/wp-content/uploads/2017/10/Monsanto-manuscriptclearance-form.pdf
- [31] Monsanto. MONGLY02145917. Email 7/19/2012, re: Genotox Review: your approval requested! Available from: https://www.baumhedlundlaw.com/pdf/monsanto-documents/Emails-Between-William-Heydens-David-Saltmiras-and-others-Discussing-Kier-Kirkland-Study.pdf

- [32] Monsanto. MONGLY01723742. Glyphosate Activities, 8/4/2015. Available from: http://baumhedlundlaw.com/pdf/monsanto-documents/18-Monsanto-Scientist-Admits-to-Ghostwriting-Cancer-Review-Paper.pdf
- [33] Williams M, Kroes R, Munro IC. Safety evaluation and risk assessment of the herbicide Roundup and its active ingredient, glyphosate, for humans. Regul Toxicol. Pharmacol. 2000;31(2):117-65.
- [34] Monsanto. MONGLY02286842. Email, 8/19/2008, re: FW: Manuscript CBTO548 for review. Available from: http://baumhedlundlaw.com/pdf/monsanto-documents/16-Internal-Email-Showing-Dr-Healy-Asked-Colleagues-to-Review-Study-That-Found-Roundup-and-Glyphosate-Adverse-Effects.pdf
- [35] Monsanto. MONGLY01238768. Reviewer Recommendation and Comments for Manuscript Number CBTO548. Available from: http://baumhedlundlaw.com/pdf/monsanto-documents/15-Peer-Review-by-Monsanto-Scientist-Recommending-Rejection-of-Study-That-Found-Glyphosate-and-Roundup-Adverse-Effects.pdf
- [36] Monsanto.MONGLY01189468. Email, 9/9/2008, re: Manuscript CBTO548. Available from: http://baumhedlundlaw.com/pdf/monsanto-documents/17-Internal-Email-Showing-Monsantos-Effort-to-Silence-Science-Re-Roundup-Adverse-Health-Effects.pdf
- [37] El-Shenawy NS. Oxidative stress responses of rats exposed to Roundup and its active ingredient glyphosate. Environ Toxicol Pharmacol. 2009;28:379-85.
- [38] Séralini G, Clair E, Mesnage R, Gress S, Defarge N, Malatesta M, Hennequin D, De Vendômois J. Long term toxicity of a roundup herbicide and a roundup-tolerant genetically modified maize. Food Chem Toxicol. 2012;50(11):4221-31.
- [39] Food and Chemical Toxicology. RETRACTED: Long term toxicity of a roundup herbicide and a roundup-tolerant genetically modified maize. Food Chem Toxicol. 2014;63:244. Available from: http://www.sciencedirect.com/science/article/pii/S0278691512005637
- [40] Séralini G, Clair E, Mesnage R, Gress S, Defarge N, Malatesta M, Hennequin D, De Vendômois J. Republished study: Long term toxicity of a roundup herbicide and a roundup-tolerant genetically modified maize. Environ Sci Eur. 2014;26:14.
- [41] Monsanto. MONGLY02063095. Email 9/26/2012, re: Letters to the Editor? Available from: http://baumhedlundlaw.com/pdf/monsanto-documents/7-Monsanto-Personnel-Discusses-Plan-Seeking-Retraction-of-Serlani-Glyphosate-Study.pdf
- [42] Monsanto. MONGLY00936725. Email 9/28/2012, re: Slides- Seralini Publication. Available from: http://baumhedlundlaw.com/pdf/monsanto-documents/14-Monsanto-Emails-Confirming-Undisclosed-Involvement-in-Successful-Retraction-of-Serlani-Study.pdf
- [43] Ferret E. Le professeur Gilles-Eric Séralini remporte le procès en diffamation face à Marianne. France 3, Basse-Normandie. France Télévisions. November 27, 2015. Available from: http://france3-regions.francetvinfo.fr/normandie/le-professeur-gilles-eric-seralini-remporte-le-proces-en-diffamation-face-marianne-864671.html
- [44] Resnik DB. Retracting inconclusive research: Lessons from the Séralini GM maize feeding study. J Agric Environ Ethics. 2015;28(4):621-33.
- [45] Monsanto. MONGLY02185742. Consulting Agreement, A. Wallace Hayes, 21 August 2012. Available from: http://baumhedlundlaw.com/pdf/monsanto-documents/10-Monsanto-Consulting-Agreement-with-Food-and-Chemical-Toxicology-Editor.pdf
- [46] Gillam C. Whitewash: The Story of a Weed Killer, Cancer, and the Corruption of Science. Washington: Island Press, 2017.
- [47] Goodman R. RG-000664-000001. Email 11/7/2012, re: FCT. Available from: https://usrtk.org/wp-content/uploads/2016/07/Goodman-Nov.-2201RG-000664-000001.pdf
- [48] Goodman R. RG-000010-000002. Email 10/7/2014, re: Question new paper glyphosate toxicity allegation. Available from: https://www.usrtk.org/wp-content/uploads/2016/07/GoodmanSriLanka1RG-000010-000001.pdf
- [49] Reynolds. A. Wallace Hayes, Reynolds Tobacco Company Inter-Office Memorandum, January 8, 1985. Available from: http://www.industrydocumentslibrary.ucsf.edu/tobacco/docs/ykfw0079
- [50] Monsanto. Email 11/30/2010, re: Questions. Available from: https://usrtk.org/wp-content/uploads/2016/01/Sachs-AR.pdf
- [51] v-Fluence. Email 3/11/2010, re: domain available. Available from: https://www.usrtk.org/wp-content/uploads/ 2016/01/uploadBruceChassy3.pdf
- [52] Monsanto. Letter to European Parliament from Philip W. Miller, 29 August 2017. Available from: https://www.greensefa.eu/files/doc/docs/9f74819f824b3975d714a22b72eb2668.pdf
- [53] Pearce N. Corporate influences on epidemiology. Int J Epidemiol. 2008;37:46-53.